Akero Therapeutics Completes Enrollment of Cohort of Cirrhotic (F4) Patients In Ongoing Balanced Study

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SAN FRANCISCO, Sept. 30, 2020 /PRNewswire/ -- Akero Therapeutics, Inc. (Nasdaq: AKRO), a cardio-metabolic non-alcoholic steatohepatitis (NASH) company developing pioneering medicines designed to restore metabolic balance and improve the overall health of NASH patients, today announced that the company has completed enrollment of a cohort of patients with NASH who have compensated cirrhosis (F4), Child-Pugh Class A.

A total of 30 cirrhotic NASH subjects with a biopsy-confirmed fibrosis score of F4 have been randomized 2:1 to receive either 50mg of efruxifermin (EFX) or placebo for 16 weeks. The primary objective of the expansion cohort is to assess safety and tolerability of EFX in NASH patients at the greatest risk of progressing to end-stage liver disease, including liver failure and liver cancer. The trial design includes various non-invasive measures of liver health, including fibrosis markers such as the Enhanced Liver Fibrosis (ELF) score and Pro-C3, as well as liver imaging.

"We are pleased to have had an opportunity early in our NASH development program to assess whether EFX has the potential to improve clinical outcomes for NASH patients with biopsy-confirmed compensated cirrhosis (F4), Child-Pugh Class A. These patients could benefit from therapeutic treatment options because they are at the highest risk of progressing to liver failure or liver cancer from NASH," said Kitty Yale, chief development officer of Akero. "Successful enrollment of this expansion cohort amidst the ongoing COVID-19 pandemic is a testimony to the attractiveness of EFX's emerging profile as a potential treatment for NASH."

The company expects to report the results of the F4 expansion cohort in the first half of 2021.

About NASH

NASH (non-alcoholic steatohepatitis) is a serious form of NAFLD (non-alcoholic fatty liver disease) and is estimated to affect 17 million Americans. NASH is closely linked to the obesity and diabetes epidemics seen around the world. NASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. As a result, NASH has become a leading cause of liver transplants in the US and Europe.

About Efruxifermin

Efruxifermin (EFX), formerly AKR-001, is Akero's lead product candidate for NASH. EFX increases insulin sensitivity, improves lipoproteins, reduces liver fat and inflammation, and reverses fibrosis. The breadth of desirable metabolic effects offers potential to address the complex, multi-organ/tissue pathogenesis of NASH, including risk factors linked to cardiovascular disease – the leading cause of death in NASH patients. Engineered to mimic the biological activity profile of native human FGF21, EFX offers convenient once-weekly dosing.

About Akero Therapeutics
Akero is a cardio-metabolic NASH company dedicated to reversing the escalating NASH epidemic by developing pioneering medicines designed to restore metabolic balance and improve overall health of NASH patients. The Company's lead product candidate, efruxifermin, has been evaluated in a 16-week Phase 2a clinical trial, the BALANCED study. Akero Therapeutics is headquartered in South San Francisco, CA. For more information, please visit www.akerotx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding the Company's business plans and objectives, including future plans or expectations for EFX, upcoming milestones, and therapeutic effects of EFX as well as the dosing, safety and tolerability of EFX; expectations regarding the design, implementation, timing, and success of its current and planned clinical trials for EFX; and the potential impact of COVID-19 on strategy, future operations, and clinical trials. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of COVID-19 on the Company's ongoing and future operations, including potential negative impacts on Akero's employees, third-parties, manufacturers, supply chain and production as well as on global economies and financial markets; the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies;

regulatory developments in the United States and foreign countries; the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's Annual Report on Form 10-K for the year ended December 31, 2019 and most recently filed Quarterly Report on 10-Q, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in Akero's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Media Contact: Carolyn Hawley, Canale Communications, carolyn@canalecomm.com, 619-849-5382; Investor Contact: Christina Tartaglia, Stern Investor Relations, 212-362-1200, akero@sternir.com